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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,877	04/19/2001	David Ian Stapleton	4050,000900	7462

7590 04/19/2004

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EXAMINER
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CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/807,877	<b>Applicant(s)</b> STAPLETON ET AL.	
	<b>Examiner</b> Jacob Cheu	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Restriction/Election**

Applicant's election of group IV, claims 22-24 with traverse, on 3/26/2004 has been received and entered into record. Applicant's argument that Ju et al. reference do not suggest or teach the instant invention is persuasive. Therefore, the lack of unity set forth from the previous Office Action is withdrawn. Accordingly, claims 14-24 are currently under examination. Claims 1-13 are cancelled.

### ***Specification Objection***

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 3, last paragraph). Applicant is requested to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01

The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words. The abstract should not exceed 25 lines of text. MPEP 608.01 (b).

### ***Claim Rejections - 35 USC § 101***

Claims 14-21 are rejected under 35 U.S.C. 101 because the claimed antibody is directed to a non-statutory subject matter, i.e. an antibody. It is suggested that applicant adds "isolated" or "purified" phrase in compliance with the requirement of 35 U.S.C. 101.

### ***Claim Rejections - 35 USC § 112***

Scope of Enablement

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 14-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polyclonal antibody, does not reasonably provide enablement for monoclonal antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

### *Antibody*

The instant invention recites an antibody directed against eNOS, in which the eNOS is phosphorylated at Ser-1177 or at Thr-495 residues. The data supports only “polyclonal” not “monoclonal” antibody developed by the inventors is capable of recognizing the phosphorylated eNOS at the 1177 and 495 position. Applicants use the phosphorylated peptides based on eNOS sequence to immunize rabbit and isolate the corresponding antibodies from the rabbit. Applicant claims “polyclonal antibodies” were raised, not monoclonal antibodies. (See page 16, second paragraph) Accordingly, the current invention should limit on “polyclonal” antibody directed against eNOS. Applicant is advised to change the claim language commensurate with the scope of the invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 14-16, 22, applicant uses the term eNOS, it is suggested that applicant spell the full term in claim 14 for clarity.

Similarly, with respect to “eNOS”, it is unclear what is the source of its origin, e.g human or bovine, or rat. Since the phosphorylated positions are particular, i.e. Ser-1177 and Thr-495, it is suggested that applicant adds “human” to the eNOS for clarity.

With respect to claim 22, line 2, “a biological sample” is vague and indefinite. It is unclear what is a biological sample in terms of its metes and bounds in the claim language.

### ***Sequence Compliance***

5. With respect to claims 17-18, applicant’s recitation of phosphorylated peptides is vague and indefinite. Applicant must use SEQ ID No in parenthesis in compliance with the sequence rule. For example, RIRTQSpFSLQER (SEQ ID No.)

### ***Conclusion***

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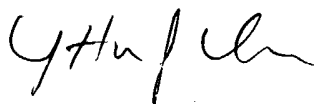
6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

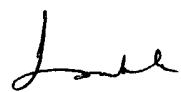
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



April 14, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
04/15/04